

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Concor 5 mg
Film-coated tablets

Concor 10 mg
Film-coated tablets

Active ingredients:

Each film-coated tablet of Concor 5 mg contains: bisoprolol fumarate 5 mg

Each film-coated tablet of Concor 10 mg contains: bisoprolol fumarate 10 mg

Inactive ingredients and allergens: See section 6 'Additional information'.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about this medicine.

If you have any further questions, consult your doctor or pharmacist.

Keep this leaflet handy. You may need to read it again.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

If you get any side effects, contact your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. See section 4 'Side effects'.

1. What is this medicine intended for

Concor is intended for treatment of stable chronic, moderate to severe heart failure with impaired systolic function (ejection fraction <35%, determined by echocardiography) in addition to ACE inhibitors and diuretics, and optionally cardiac glycosides.

Additionally, Concor is intended for treatment of hypertension and coronary heart disease (angina pectoris).

Therapeutic group:

Beta blocking agents, selective

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to bisoprolol or to any of the other ingredients in this medicine (see section 6 'Additional information')
- You suffer from severe asthma
- You suffer from severe blood circulation problems in your limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue
- You suffer from untreated phaeochromocytoma, which is a rare tumour of the adrenal gland
- You suffer from metabolic acidosis, which is a condition when there is too much acid in the blood
- You suffer from acute heart failure
- You suffer from worsening heart failure requiring injection of medicines into a vein, that increase the force of contraction of the heart
- You suffer from a slow heart rate
- You suffer from low blood pressure
- You suffer from certain heart conditions causing a very slow heart rate or irregular heartbeat
- You suffer from cardiogenic shock (originating in the heart), which is a serious heart condition causing low blood pressure and circulatory failure

Special warnings about using this medicine

Before starting treatment with Concor, tell your doctor if:

- You suffer from diabetes
- You are fasting strictly
- You suffer from certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (Prinzmetal's angina)
- You suffer from kidney or liver problems
- You have less severe blood circulation problems in your limbs
- You suffer from chronic lung disease or less severe asthma
- You have a history of a scaly skin rash (psoriasis)
- You suffer from tumours of the adrenal gland (phaeochromocytoma)
- You suffer from thyroid disorders

Your doctor may want to take special care (for example give additional treatment or perform more frequent checks).

In addition, tell your doctor if you are going to have:

- desensitization therapy (for example for the prevention of hay fever), because Concor may make it more likely that you experience an allergic reaction, or such reaction may be more severe
- anaesthesia (for example for surgery), because Concor may influence how your body reacts to anesthesia process.

If you suffer from chronic lung disease or less severe asthma, inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise or similar effects when using Concor.

Children and adolescents

This medicine is not recommended for use in children and adolescents.

Tests and follow-up

Treatment with Concor requires regular monitoring by your doctor. Monitoring is particularly necessary at the beginning of treatment, during the dose increase and when you stop treatment.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Do not take the following medicines along with Concor without consulting your doctor:

- Certain medicines used to treat irregular or abnormal heartbeat (Class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, propafenone).
- Certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (calcium antagonists such as verapamil and diltiazem).
- Certain medicines used to treat high blood pressure such as clonidine, methyl dopa, moxonidine, rilmenidine. However, **do not stop taking these medicines** without checking with your doctor first.

Check with your doctor before taking the following medicines with Concor; your doctor may need to check your condition more frequently:

- Certain medicines used to treat high blood pressure or angina pectoris (dihydropyridine-type calcium antagonists such as felodipine and amlodipine).
- Certain medicines used to treat irregular or abnormal heartbeat (Class III antiarrhythmic medicines such as amiodarone).

- Beta-blockers applied locally (such as timolol eye drops for glaucoma treatment).
- Certain medicines used to treat Alzheimer's disease or glaucoma (for example, parasympathomimetics such as tacrine or carbachol) or medicines that are used to treat serious heart problems (sympathomimetics such as isoprenaline and dobutamine).
- Antidiabetic medicines including insulin.
- Anaesthetic agents (for example during surgery).
- Digitalis, used to treat heart failure.
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac).
- Any medicine, which can lower blood pressure as a desired or undesired effect such as antihypertensives, certain medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline), certain medicines used to treat epilepsy or during anaesthesia (barbiturates such as phenobarbital), or certain medicines to treat mental illness characterized by a loss of contact with reality (phenothiazines such as levomepromazine).
- Mefloquine, used for prevention or treatment of malaria.
- Depression treatment medicines called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide.

Using this medicine and food

Take the tablet in the morning with some water, with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult your doctor or pharmacist before using medicines.

There is a risk that use of Concor during pregnancy may harm the fetus. If you are pregnant or planning to become pregnant, tell your doctor, and they will decide whether you can take Concor during pregnancy.

It is not known if bisoprolol passes into breast milk. Therefore, breastfeeding is not recommended during therapy with Concor.

Driving and using machines

Your ability to drive or use machinery may be affected depending on how well you tolerate the medicine. Be especially cautious at the start of treatment, when the medication is changed or in combination with consumption of alcohol.

3. How to use this medicine

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take the medicine. The dosage and treatment regimen will be determined by the doctor only.

Treatment with Concor must be started at a low dose and increased gradually.

Your doctor will decide how to increase the dose.

The recommended dosage is usually:

Treatment of stable chronic heart failure

This will normally be done in the following way:

- 1.25 mg bisoprolol once daily for one week
- 2.5 mg bisoprolol once daily for one week
- 3.75 mg bisoprolol once daily for one week
- 5 mg bisoprolol once daily for four weeks
- 7.5 mg bisoprolol once daily for four weeks
- 10 mg bisoprolol once daily for maintenance (on-going) therapy.

The maximum recommended daily dose is 10 mg bisoprolol. Depending on how well you tolerate the medicine, your doctor may decide to lengthen the time between dose increases.

If your condition gets worse or you no longer tolerate the drug, it may be necessary to reduce the dose again or to interrupt treatment.

In some patients a maintenance dose lower than 10 mg bisoprolol may be sufficient. Your doctor will tell you what to do.

If you have to stop treatment entirely, your doctor will usually advise you to reduce the dose gradually, as otherwise your condition may become worse.

Treatment of hypertension

The recommended dose regimen is 5 mg once daily. In cases of mild hypertension, your doctor may determine that a dosage of 2.5 mg once daily is sufficient.

If necessary, your doctor may instruct you to increase the dosage of the medicine to 10 mg once daily.

The maximum recommended dose is 20 mg once daily.

Treatment of angina pectoris

The recommended dose regimen is 5 mg once daily.

If the response is insufficient, your doctor may instruct you to increase the dosage of the medicine to 10 mg once daily.

The maximum recommended dose is 20 mg once daily.

Dosage in patients with liver and kidney function disorders

In patients with liver or kidney function disorders of mild to moderate severity, no dosage adjustment is normally required. In patients with severe liver or kidney function disorders, do not exceed a daily dose of 10 mg.

Use in elderly patients

No dosage adjustment is required.

Use in children and adolescents

Concor is not intended for use in children, as efficacy and safety have not been tested in this age group.

Do not exceed the recommended dose.

Treatment with Concor is usually long term.

There is no information on crushing or chewing the tablet. The scored tablets can be divided into two equal doses.

If you have accidentally taken a higher dose or if a child has accidentally swallowed some medicine, immediately go to a hospital emergency room and bring the medicine package with you.

Symptoms of an overdose may include slowed heart rate, severe difficulty in breathing, feeling dizzy or trembling (due to decreased blood sugar).

If you forget to take the medicine at the scheduled time, do not take a double dose to "make up" for the forgotten dose. Take your usual dose the next morning.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not change or stop the treatment with this medicine without consulting your doctor. Otherwise your condition could become worse.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Concor may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

To prevent serious reactions, contact a doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

The most serious side effects are related to the heart function:

- Slowing of heart rate (may affect more than 1 in 10 patients)
- Worsening of heart failure (may affect up to 1 in 10 patients)
- Slow or irregular heartbeat (may affect up to 1 in 100 patients)

If you feel dizzy or weak, or have breathing difficulties - contact your doctor as soon as possible.

Additional side effects:

Common side effects (may affect up to 1 in 10 people):

- Tiredness, feeling weak, dizziness, headache
- Feeling of coldness or numbness in hands or feet
- Low blood pressure
- Stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation

Uncommon side effects (may affect up to 1 in 100 people):

- Sleep disturbances
- Depression
- Dizziness when standing up
- Breathing problems in patients with asthma or chronic lung disease
- Muscle weakness, muscle cramps

Rare side effects (may affect up to 1 in 1,000 people):

- Hearing problems
- Allergic runny nose
- Reduced tear flow
- Inflammation of the liver which can cause yellowing of the skin or whites of the eyes
- Certain blood test results for liver function or fat levels differing from normal
- Allergy-like reactions such as itching, flush, rash. You should see your doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing
- Impaired erection
- Nightmares, hallucinations
- Fainting

Very rare side effects (may affect up to 1 in 10,000 people):

- Irritation and redness of the eye (conjunctivitis)
- Hair loss
- Appearance or worsening of scaly skin rash (psoriasis); psoriasis-like rash

If a side effect occurs, if any side effect worsens or if you suffer from a side effect not mentioned in this leaflet, consult with your doctor.

Side effects can be reported to the Ministry of Health by clicking the link 'Reporting Side Effects of Drug Treatment' found on the Ministry of Health home page (www.health.gov.il) which directs you to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. How to store the medicine

- Prevent poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use, in order to protect the environment.

6. Additional information

- In addition to the active ingredients, this medicine also contains:

Concor 5 mg:

Tablet -

Calcium hydrogen phosphate anhydrous, maize starch, microcrystalline cellulose, crospovidone, magnesium stearate, silica colloidal anhydrous

Coating -

Hypromellose 2910/15, titanium dioxide (E171), macrogol 400, dimethicone 100, iron oxide yellow (E172)

Concor 10 mg:

Tablet -

Calcium hydrogen phosphate anhydrous, maize starch, microcrystalline cellulose, crospovidone, magnesium stearate, silica colloidal anhydrous

Coating -

Hypromellose 2910/15, titanium dioxide (E171), macrogol 400, dimethicone 100, iron oxide yellow (E172), iron oxide red (E172)

- **What the medicine looks like and contents of the pack:**

Concor 5 mg tablets are yellowish to white, heart-shaped film-coated tablets, scored on both sides of the tablet.

The tablets are packaged in a blister pack made of aluminium foil and coated in rigid PVC and are stored in a cardboard carton.

Each pack contains 30, 50, 100 or 300 tablets.

Concor 10 mg tablets are pale orange to light orange, heart-shaped film coated tablets, scored on both sides of the tablet.

The tablets are packaged in a blister pack made of aluminium foil and coated in rigid PVC and are stored in a cardboard carton.

Each pack contains 30, 50, 100 or 300 tablets.

Not all pack sizes may be marketed.

- **License holder's name and address:** Merck Serono Ltd., 18 HaKishon St., Yavne 81220.
- **Manufacturer's name and address:** Merck Healthcare KGaA, Darmstadt, Germany.
- Revised in May 2021 according to MOH guidelines.

- Registration number of the medicine in the Ministry of Health National Drug Registry:
Concor 5 mg 057-79-25169-01
Concor 10 mg 057-78-25170-01